Exhibit #4 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: _____

1. Date of Submission: March 14, 2013

OCT 0 3 2013

2. Sponsor

Guangdong Baihe Medical Technology Co., Ltd.
No. 89, Taoyuan East Road, Nanhai, Foshan, Guangdong, 528225, China

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3. Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu
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4. Proposed Device Identification

Common Name: Disposable Balloon-retention Catheter
Proposed Device Name: Disposable Silicone Foley Catheter
Proposed Device Type: Two-way and Three way

Regulatory Information:
Classification Name: Catheter, Retention type, Balloon
Classification: II
Product Code: EZL
Regulation Number: 21 CFR 876.5130
Review Panel: Gastroenterology/Urology
Intended Use Statement:

Two-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage for urological use only; the indwell time of the proposed device is no more than 30 days.
Three-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage and bladder irrigation for urological use only; the indwell time of the proposed device is no more than 30 days.

5. Predicate Device Identification

510(k) Number: K981612
Product Name: Rochester Medical Corporation All Silicone Foley Catheter
Manufacturer: Rochester Medical Corporation

6. Device Description

The Disposable Silicone Foley Catheter is available in two types, two-way disposable silicone Foley catheter and three-way disposable silicone Foley catheter.

The two-way disposable silicone Foley catheter is composed of a double lumen tube, a double lumen hub, one balloon and a tip.

The three-way disposable silicone Foley catheter is composed of a triple lumen tube, a triple lumen hub, one balloon and a tip.

The proposed device is supplied in French size ranging from 6 to 26. It is available in 310mm and 400mm length with various balloon sizes. The devices are applied for male and female; the 6Fr, 8Fr and 10Fr catheters are for pediatric, and others are for adult.

The Disposable Silicone Foley Catheter is provided EO sterilized as a single used device.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ASTM F88-09, Standard Test Method for Seal Strength of Flexible Barrier Materials

ASTM F 1140-07 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Package for Medical Applications

ASTM F1929-98(2004) Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration

ISO 11135-1:2007 Sterilization of health care products- Ethylene oxide- Part 1: Requirements for development, validation and routing control of a sterilization process for medical devices;

USP <85> Bacterial Endotoxin Limit

ASTM F 623-99 (2006) Standard Performance Specification for Foley Catheter

ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro Cytotoxicity

ISO 10993-10:2010, Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization

ISO 10993-11:2006, Biological evaluation of medical devices Part 11: Tests for systemic toxicity

ISO 10993-6:2007, Biological evaluation of medical devices- Part 6: Tests for local effects after implantation

The Disposable Silicone Foley Catheter meets the following performance requirements per testing conducted according to ASTM F623-99 (2006):

Flow Rate

Balloon Integrity

Balloon Response to Pullout

Balloon Volume Maintenance

Manufacturing Tolerances for Catheter Tip, Balloon and Shaft Diameters

Balloon Deflation Reliability

8. Substantially Equivalent Conclusion

Tab. 3-1 Comparison between proposed device and predicated device

ITEM	Proposed Device	Predicate Device K981612
Product Code	EZL	EZL
Regulation No.	21 CRF 876.5130	21 CRF 876.5130
Class	II	II
Intended Use	Same	Same
Target population	Pediatric, male and female	Same
Lumen	Two-way and three-way	Same
French size	Two-way: 6Fr, 8Fr, 10Fr, 12Fr, 14Fr, 16Fr, 18Fr, 20Fr, 22Fr, 24Fr and 26Fr Three-way: 16Fr, 18Fr, 20Fr, 22Fr, 24Fr and 26Fr	Same
Balloon size	1.5cc, 3cc, 5cc, 10cc, 15cc, 20cc, 30cc	Similar
Length	310mm and 400mm	Similar
Sterile	Yes	Yes
Single use	Yes	Yes

The proposed device, Disposable Silicone Foley Catheter, is determined to be Substantially Equivalent (SE) to the predicate device, Rochester Medical Corporation All Silicone Foley Catheter (K981612), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 3, 2013

Guangdong Baihe Medical Technology Co., Ltd.
% Diana Hong
General Manager
MID-LINK Consulting Co., Ltd.
P.O. Box 120-119
Shanghai
China 200120

Re: K130908
Trade/Device Name: Disposable Silicone Foley Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: August 29, 2013
Received: September 4, 2013

Dear Diana Hong,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit #3 Indications for Use

510(k) Number: K130908
Device Name: Disposable Silicone Foley Catheter

Indications for Use:

Two-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage for urological use only; the indwell time of the proposed device is no more than 30 days.
Three-way Disposable Silicone Foley Catheter: Urethral catheterization for bladder drainage and bladder irrigation for urological use only; the indwell time of the proposed device is no more than 30 days.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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